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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Michael West

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EXAMINER

OLSON, ERIC

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/524,048	Applicant(s) WEST ET AL.	
	Examiner Eric S. Olson	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4-28 is/are pending in the application.
- 4a) Of the above claim(s) 6-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, and 25-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/7/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 6, 2008 has been entered.

This office action is a response to applicant's amendment and arguments submitted March 8, 2008 wherein claims 1, 2, 4, 5, and 27 are amended, claim 3 is cancelled, and new claim 28 is introduced. This application is a national stage application of PCT/AU03/01008, filed August 8, 2003, which claims priority to foreign application AU2002950657, filed August 8, 2002.

Claims 1, 2, and 4-28 are pending in this application.

Claims 1, 2, 4, 5, and 25-28 as amended are examined on the merits herein.

Applicant has requested rejoinder of withdrawn claims 6-24 on the grounds that the generic structure recited in claim 1 is a special technical feature over the prior art. However, as discussed below, claim 1 is still rejected over the prior art, and is therefore not a special technical feature over the art. For this reason rejoinder is not granted and claims 6-24 are still withdrawn.

Applicant's amendment, submitted March 6, 2008, with respect to the rejection of instant claims 1, 2, 4, 25, and 26 under 35 USC 103(a) for being obvious over Sas et al., has been fully considered and found to be persuasive to remove the rejection as the base claim has been amended to exclude compositions containing two dissimilar C1-C3 alkyl groups at positions R2 and R3, for example methyl and ethyl. Any substitution of a group larger than C3 for methyl in this structure would be sufficiently different from the base structure so as not to be obvious to one of ordinary skill in the art. Therefore the rejection is withdrawn.

Applicant's arguments, submitted March 6, 2008, with respect to the rejection of instant claims 1, 2, 4, and 25-27 under 35 USC 103(a) for being obvious over Johnson et al. in view of Carey et al., has been fully considered and found to be persuasive to remove the rejection as the synthetic scheme of Johnson et al. is seen to be sufficiently complex that arbitrary substitution of protecting groups would not be expected to yield a suitable intermediate for this scheme. Therefore the rejection is withdrawn.

Applicant's arguments, submitted March 6, 2008, with respect to the rejection of instant claims 1, 2, 4, and 25-27 under 35 USC 103(a) for being obvious over Fukase et al. in view of Carey et al., has been fully considered and found to be persuasive to remove the rejection as the synthetic scheme of Fukase et al. is seen to be sufficiently complex that arbitrary substitution of protecting groups would not be expected to yield a suitable intermediate for this scheme. Therefore the rejection is withdrawn.

Claim Objections

Claim 5 is objected to because of the following informalities: it depends in part from cancelled claim 3. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's amendment submitted January 8, 2007 with respect to the aforementioned claims has been fully considered and but is deemed to insert **new matter** into the claims since the specification as originally filed does not provide support for the proviso that when two of the groups R2 to R5 are ether, they may not both be C1-C3 n-alkyl. Specifically, there is no basis for excluding the range of compounds in which two or R2-R5 are C1-C3 n-alkyl. Although methyl and ethyl are mentioned as possible embodiments of R in groups of the formula –OR, the group of compounds wherein two of R2-R5 are –O-(C1-C3 n-alkyl) There is no basis for written description of an exclusionary proviso excluding an embodiment that is never explicitly mentioned in the specification. As the instant specification as filed contains no

description of this class of compounds as a discrete grouping the specification as originally filed does not provide support for the subject matter of instant claims 1, 2, 4, and 5. See *in re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972).

The following new grounds of rejection are introduced:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 25, 26, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Papageorgiou et al. (PCT international publication WO00/42057, reference included with PTO-892)

Papageorgiou et al. discloses monosaccharide building blocks derived from 5 or 6-carbon pyranose and furanose sugars and aminosugars having an anomeric leaving group that can be a thioalkyl group, and in which the remaining hydroxyl and amino groups are protected by orthogonal protecting groups. (p. 4 lines 14-31) It is noted that the orthogonal classes of protecting groups exemplified by Papageorgiou et al. include amino protecting groups such as dichlorophthaloyl and pentenyl that fall within the limits of N(Y)Z in instant claim 1, reduction sensitive OH-protecting groups such as trifluoromethyl and trichloromethoxymethyl, base-sensitive protecting groups such as ethoxyethyl and cyanoethyl, hydrogenation-sensitive groups such as naphthylmethyl and substituted naphthylmethyl, (group Y17 in claim 26) photolabile protecting groups

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such as o-nitrobenzyl, (group Y23 in claim 26) and relay deprotection labile groups such as methylthiorthyl, acyloxybenzyl, and benzylthioethyl. (pp. 6-7) Papageorgiou et al. also includes examples wherein a protected 2-amino-2-deoxysugar of this generic formula is synthesized by a route that involves intermediates having a combination of protected -OR groups and unprotected -OH groups, just like the instantly claimed partially protected sugars. (p. 14 example 2, compounds 3 and 4, p. 24 example 5 compounds 22 and 23) Note that these examples use a thiomethyl activating group at the C-1 position, just as is recited in instant claim 25, group X1. Papageorgiou et al. does not specifically exemplify a compound having the specific protecting groups recited in instant claim 1 and also having one or two free hydroxyl groups.

It would have been obvious to one of ordinary skill in the art at the time of the invention to make the compounds of Papageorgiou et al. having hydroxyl and amino protecting groups falling within the limitations of instant claim 1 (for example pentenyl, trifluoromethyl, and o-nitrobenzyl) by a stepwise protection pathway involving an intermediate that has one or two unprotected hydroxyl groups, similar to those practiced in examples 2 and 5 of Papageorgiou et al. One of ordinary skill in the art would have concluded that any of the compounds encompassed by the general structures taught by Papageorgiou et al. could be produced by a variation of the synthetic methods taught by Papageorgiou et al. One of ordinary skill in the art would have been motivated to see the thiomethyl anomeric leaving group in position R1 because this group is specifically exemplified in the examples provided by Papageorgiou et al. One of ordinary skill in the art would reasonably have expected success because all of the protecting groups used

in the obvious embodiments are explicitly identified by Papageorgiou et al. as being orthogonal protecting groups usable in the compounds and methods described therein.

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments submitted March 6, 2008, with respect to the previous rejections under 35 USC 103 of various claims as obvious over Johnson et al. or Fukase et al. in view of Carey et al. have been fully considered as they apply to the above rejection and are not found to be persuasive to remove the rejection. The previous rejections have been withdrawn in view of Applicant's arguments that he disclosed synthetic schemes are complex and involve many different chemical transformations that would render all but a few select protecting group combinations unworkable. Thus one of ordinary skill in the art would not have expected success in arbitrarily selecting various orthogonal protecting groups from a general prior art reference such as Carey et al. that merely discloses the state of the protecting group art without reference to the facts of the specific synthesis. However, with regard to Papageorgiou et al., one of ordinary skill in the art would have expected that the various protecting groups disclosed therein could be substituted in the disclosed synthetic scheme because they are explicitly identified in the same reference as being orthogonal protecting groups useful as protecting groups in the specific compound and methods discussed in the reference. Thus the facts of the case are different than with the Johnson et al. and Fukase et al. references, so the rejection is maintained.

Claims 1, 2, 4, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US patent 4495346, cited in PTO-892)

Anderson et al. discloses a method of making a disaccharide utilizing a monosaccharide building block (labeled as III) having a structure that overlaps with the instant claims. (column 1 line 43 – column 2 line 67, wherein R = C7-C9 alkyl or hydroxyalkyl, R = phenyl, benzyl, (group X10 from instant claim 25) and R4 = hydrogen) Anderson et al. does not explicitly exemplify a compound in which R is a C7-C9 alkyl. It would have been obvious to one of ordinary skill in the art at the time of the invention to make the compound of the instant claims to use in the synthesis described by Anderson et al. wherein R is a C7-C9 alkyl. One of ordinary skill in the art would have recognized that this section of the full range (C7-C19) disclosed by Anderson et al. would have been useful in synthesizing the disaccharides of Anderson et al. When the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2144.05 [R-1].

Therefore the invention taken as a whole is *prima facie* obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, and 25-27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-21 of copending Application No. 10/419070. (Cited in PTO-892 as USPTO pre-grant publication 2003/0332766, herein referred to as '070) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 16-21 of '070 anticipate the claimed invention.

Specifically, claim 16 and its dependent claims are drawn to a range of compounds having a structure that falls within the limits of instant claims 1, 2, and 5. Furthermore, these compounds have a naphthylmethyl anomeric protecting group, (group X7 in instant claim 25) a carboxymethyl ether protecting group, (group Y8 in instant claim 26) and a benzoyl, biphenylcarbonyl, or t-butylcarbonyl amine protecting group, (groups Z13, Z36, and Z6 of claim 27 respectively) thus anticipating claims 25-27. Therefore the claimed invention is anticipated by claims 16-21 of '070.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. However, this rejection cannot be held in abeyance as the '070 application has been allowed.

Claims 1, 2, 4, and 25-27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-18 of copending Application No. 10/813737. (unpublished, herein referred to as '737) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 14-18 of '737 anticipate the claimed invention.

Specifically these claims are drawn to pyranose compounds having N(Y)Z, OR, and OH groups as described in instant claims 1, 2, 4, and 5. Specific groups include methoxy, ethoxy, benzyloxy, and phenoxy groups in position R₁ according to instant claim 25, groups such as methyl, ethyl, benzyl, carboxybenzyl, and carboxymethyl in positions R₃ and R₄ falling within the limits of instant claim 26, and groups such as ethyl, phenyl, imidazolyl, piperidine, or aminophenyl falling within the limits of instant claim 27. Therefore claims 14-18 of '737 anticipate the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
6/16/2008

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623